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FDA Approves Erbitux for Colorectal Cancer

FDA today approved Erbitux (cetuximab) to treat patients with advanced colorectal cancer that has spread to other parts of the body. Erbitux is the first monoclonal antibody approved to treat this type of cancer and is indicated as a combination treatment to be given intravenously with irinotecan, another drug approved to fight colorectal cancer, or alone if patients cannot tolerate irinotecan.

Erbitux was approved under FDA's accelerated approval program, which allows FDA to approve products for cancer and other serious or life-threatening diseases based on early evidence of a product's effectiveness. Although treatment with Erbitux has not been shown to extend patients' lives, it was shown to shrink tumors in some patients and delay tumor growth, especially when used as a combination treatment.

Erbitux is a genetically engineered version of a mouse antibody that contains both human and mouse components. (Antibodies in the body are substances produced by the immune system to fight foreign substances.) It can be produced in large quantities in the laboratory. This new monoclonal antibody is believed to work by targeting a natural protein called "epidermal growth factor receptor" (EGFR) on the surface of cancer cells, interfering with their growth.

For patients with tumors that express EGFR and who no longer responded to treatment with irinotecan alone or in combination with other chemotherapy drugs, the combination treatment of Erbitux and irinotecan shrank tumors in 22.9% of patients and delayed tumor growth by approximately 4.1 months. For patients who received Erbitux alone, the tumor response rate was 10.8% and tumor growth was delayed by 1.5 months.

Colorectal cancer -- cancer of the colon or rectum -- is the third most common cancer affecting men and women in the U.S. and, according to the Centers for Disease Control and Prevention (CDC), and is the second leading cause of cancer-related death. Colorectal cancer is also one of the most commonly diagnosed cancers in the U.S.; approximately 147,500 new cases were diagnosed in 2003.

"In their review activities, FDA staff work hard to ensure doctors and patients can have confidence in the safety and effectiveness of new therapies such as Erbitux," said Mark B. McClellan, M.D., Ph.D. "FDA believes it is crucial for cancer patients to have many proven treatment options in their battle against this disease."

The efficacy and safety of Erbitux alone or in combination with irinotecan were studied in a randomized, controlled trial with 329 patients and also in combination with irinotecan in 138 patients in which all patients received both drugs. Erbitux was further evaluated as a single agent in a third clinical trial with 57 patients. Safety data from an additional 111 patients treated only with Erbitux was also evaluated. All of the trials included patients with EGFR-expressing metastatic colorectal cancer, whose disease had progressed after receiving irinotecan.

The manufacturer of Erbitux, ImClone Systems Incorporated, Branchburg, N.J., submitted their original request for approval in several sections between June 28 and October 31, 2001. Subsequent to ImClone's original submissions, FDA determined that their application could not be reviewed because approximately half of the patients (94) studied had not failed the approved treatments for colon cancer; and important information about the safety and effectiveness of Erbitux in a portion of the remaining patients (102) was missing. In their new request for approval on August 14, 2003, Imclone submitted the results of a large, well-run trial that included 329 patients as well as the results of the earlier two studies. For the studies submitted in their original 2001 request for approval, ImClone successfully collected substantial amounts of missing information from hospital records and other sources.

Two studies involving approximately 2000 patients are currently underway to assess the clinical benefits of Erbitux. These studies are specifically examining the ability of Erbitux to stop the progression of colorectal cancer and to extend the amount of time patients survive with the disease.

Erbitux can cause serious side-effects, usually during the administration of the first treatment, which may include difficulty breathing and low blood pressure. Infrequent interstitial lung disease (ILD) has been reported; however, it is difficult to determine if Erbitux caused ILD. ILD occurs when the lung becomes stiff due to scarring of the tissue between the air sacs of the lungs.

Other more common side-effects of Erbitux treatment include acne-like rash, dry skin, tiredness or weakness, fever, constipation, and abdominal pain.

Erbitux will be distributed and marketed by Bristol-Myers Squibb Company, Princeton, N.J.

FDA also today approved a test kit, manufactured by DakoCytomation California, Inc., that is used by doctors to analyze a colon tissue sample. The kit detects a protein in the body (HER-1) that stimulates cancerous tissue cell growth. Presence of this protein indicates that a patient is eligible for colon cancer treatment with Erbitux.

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